



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Ninth Annual Drug Information Association/Food and Drug Administration Statistics Forum--2015; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA), in cosponsorship with the Drug Information Association (DIA), is announcing a public conference entitled “Ninth Annual DIA/FDA Statistics Forum--2015”. The purpose of the conference is to discuss relevant statistical issues associated with the development and review of therapeutic drugs and biologics. A primary focus for this meeting will be to establish an ongoing dialogue regarding FDA’s “Critical Path” initiative--emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trial data and measuring the progress being made in designing and implementing innovative solutions.

DATES: The public conference will be held from April 20, 2015, to April 22, 2015, from 8:30 a.m. to 5 p.m. each day.

ADDRESSES: The public conference will be held at the Marriott Bethesda North Hotel and Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852, 301-822-9200.

FOR FURTHER INFORMATION CONTACT: Ellen Diegel, Drug Information Association, 800 Enterprise Rd., Horsham, PA 19044, 215-442-6100, Ellen.Diegel@diahome.org; or Stephen Wilson, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3630, Silver Spring, MD 20993-0002, 301-796-0579, Stephen.Wilson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This annual FDA/DIA statistics forum will be a unique, open, international forum for statisticians and clinicians from industry, academia, contract research organizations, and Government Agencies. Meeting participants will learn, discuss, and collaborate on the current and emerging statistical methodologies and quantitative approaches used by sponsors to provide evidence for the approval of new therapies.

The goals of the program are to:

- Explore and implement innovative statistical solutions to issues associated with the regulatory review of therapeutic drugs and biologics.
- Describe the application of statistical methodologies and thinking to the development of new therapeutic biologics and drugs.
- Assess the impact of regulations and guidance on statistical practice.
- Discuss ideas for improving the communication between industry statisticians and FDA reviewers.

A description of the planned activities of the working groups can be found at <http://www.diahome.org/en-US/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=3630578&EventType=Meeting>.

II. Registration and Accommodations

A. Registration

To register, please submit the registration form online at <http://www.diahome.org/en-US/Meetings-and-Training/Find-Meetings-and-Training/Meeting-Details.aspx?ProductID=3630578&EventType=Meeting>. (FDA has verified this Web site address but is not responsible for changes to the Web site after this document publishes in the Federal Register.) Seats are limited, and conference space will be filled in the order in which registrations are received. On-site registration will be available to the extent that space is available on the day of the conference. The costs of registration for different categories of attendees are as follows:

Category	Cost
Industry Representatives	\$1,440
Charitable Nonprofit/Academic (Full time)	\$720
Government (Full time)	\$430
Tutorial Fees	\$405

All registrants will be required to pay the applicable fee, with the exception of a limited number of speakers/organizers who will have a complimentary registration. (Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to Ellen.Diegel@diahome.org.) Registration fees cover the costs of facilities, materials, and food functions.

B. Accommodations

Attendees are responsible for their own accommodations. Reservations may be made online via the conference hotel reservation page at

<https://www.tphousing.com/ph2/startres.aspx?EICode=3132&Attcode=72>.

The Marriott Bethesda North Hotel and Conference Center has a limited number of rooms available at the discounted rate of \$199 per night until April 3, 2015, or until the block is filled. To receive this rate, attendees are asked to make reservations using the link to the hotel reservation page or by calling 855-355-0302 or 212-532-1660. If calling, please select the first option for "Hotel Reservations" and inform the phone agent that you are making a reservation for "Event #15008".

If you need special accommodations because of disability, please contact Ellen.Diegel@diahome.org at least 7 days before the meeting.

Dated: March 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-06702 Filed: 3/24/2015 08:45 am; Publication Date: 3/25/2015]